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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,187	04/21/2000	Amy E. Baker	425802000200	7012

25226 7590 12/22/2003

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/557,187	BAKER, AMY E.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-11,13 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-11,13 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 7-11, 13, and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "likelihood" renders claims 1 and 11 vague and indefinite, as the claim fails to affirmatively recite what the physical property of the claimed composition. It is not clear whether the composition actually causes, eliminates, or reduces the nasal irritation or coughing. It is also questionable whether the phrase "whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced" appears to be a motivation to formulate the composition above the pH of 5, in which case, the claim should be directed to a method (e.g., method of reducing nasal irritation or coughing)

rather than a composition. For the examination purposes, the limitation will be treated as a physical property of the composition.

The term "above about" in line 4 of claims 1 and 11 renders the claims vague and indefinite. It is not clear what pH is within the claimed range of "above about" 5 (4, or 5.5).

The remaining claims are rejected as depending on definite base claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak (DE003127590 A1) in view of Briggs et al. (US 5976521) ("Briggs") and Stone (US 4322020).

The claimed invention is a composition in the form of fine mist spray comprising 0.01-20 % by weight of the solution and having pH above about 5, and a method of using the composition to treat acne. The phrase in claim 1 "for administration as such only to non-facial body skin to treat acne or acneform condition" is a preamble reciting intended use of the composition, and no patentable weight is given to the term. The phrase in the same claim "whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced" is also viewed a property that is necessarily present in a composition comprising salicylic acid which has pH of "above about 5". It cannot be said a composition which contains salicylic acid in alcohol/water vehicle and has the pH

of the instant invention somehow does not reduce nasal irritation and coughing which the present invention does.

Kozak teaches that it is well known in the art to formulate a topical composition comprising salicylic acid and additional active ingredients into sprayable form. See abstract. The reference teaches using 0.02-6 g of salicylic acid and resorcinol. The method of treating acne with the prior art composition is taught. See instant claim 20.

Kozak fails to teach the pH of the composition and using "fine mist pump spray". The reference also fails to teach aqueous alcoholic solvent.

Briggs teaches an anti-acne composition comprising salicylic acid. See abstract. To deliver salicylic acid in aqueous solution but without the salicylic acid precipitating out of solution, the reference teaches that the salicylic acid is dissolved in aqueous/alcoholic solution. See col. 1, line 63 – col. 2, line 37. See instant claims 7 and 8. Briggs further teaches that the preferred pH of the final aqueous/alcoholic anti-acne active solution is preferably in the range of about 1-7. See col. 3, lines 37 – 47. See instant claims 1, 2, 4, 5, 11, and 15. Ethyl alcohol is preferred and used in the illustrated formulation for the aqueous phase, which contains salicylic acid. See col. 3, lines 1 – 47; col. 11, lines 35 – 40. See instant claims 7, 8, 16, and 17. From about 0.1 to about 10 % of salicylic acid is used. See col. 2, lines 61 – 67; instant claim 10.

Briggs fails to teach fine mist pump spray.

Stone teaches an invertible fine mist pump sprayer which is useful to dispense cosmetic or pharmaceutical compositions. See col. 1, line 9 – col. 2, line 65. The reference teaches that pump sprays are preferred over aerosols because of the

clogging problem in the aerosol valves and environmental concerns. See col. 1, lines 22-35. In Example 1, the reference describes a topical anesthetic solution spray having an average particle size of approximately 200 microns when the viscosity of the solution is 38 cps. at 20 °C.

While the particle size does not expressly meet the limitation of instant claim 2, the reference teaches "the particle size of the spray will vary with the rheology of the liquid being sprayed as well as with the orifice size." See col. 5, lines 44 – 49. It is further disclosed, "the lower the viscosity of the liquid and the smaller the orifice size, the smaller the particle size obtained." The reference even teaches that for applying cosmetics, spray particle size of 50-500 microns is desirable. See col. 1, lines 18-21. Thus it would have been obvious to a routineer to produce the spray in the desired range for topical formulations with the expectation that a low viscous solution would produce smaller spray particles.

Given the teaching of formulating salicylic acid topical composition in the form of spray, one having ordinary skill in the art at the time the invention was made to have looked to the prior arts such as Stone because of the expectation of successfully producing a spray with the desired spray effects (fine spray particles, usability from various angles, etc.) while eliminating the problems with aerosol value and environmental concerns.

2. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak, Briggs, and Stone as applied to claims 1, 2, 4, 5, 7- 8, 10, 11, 13, 15-17, and 20 as above, and further in view of Guang Lin et al. (US 5612324) ("Guang Lin").

The combined references fail to teach denatured ethyl alcohol.

Guang Lin teaches anti-acne composition comprising salicylic acid in aqueous/ethanol carrier. See Examples. SD (specifically denatured) alcohol is used in the formulation. See instant claims 9 and 18.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the aqueous alcohol vehicle for salicylic acid in the combined references by substituting the ethanol with conventionally used denatured ethanol as motivated by Guang Lin because of an expectation of successfully producing similar salicylic acid aqueous solution.

3. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak, Brigg, and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 as above, and further in view of Fitzjarrell (US 5759559).

The combined references fails to specifically teach using salicylic acid as the sole anti-acne active ingredient.

Fitzjarrell teaches that salicylic acid is used and well-known anti-acne agent used for mild acne. See col. 1, lines 17 – 28; col. 2, lines 28 – 36.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray composition of the combined references by using salicylic acid alone as the sole active anti-acne ingredient because of the for the anti-acne actives employed in the patent because of the expectation of successfully producing a mild anti-acne spray solution.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak, Briggs, and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 above, and further in view of and Sciarra (Remington: Practice of Science and Pharmacy).

The combined references fail to teach the volume of spray per actuation.

Sciarra teaches that topical aerosols have been used for preparations for the treatment of acne. See p. 1676, 1st par. He also teaches that for topical sprays particles are produced in size from 50-200 μm. See p. 1677, 4th par. See instant claim 2. The reference further teaches that for a typical metered-dose aerosol delivery system for pharmaceuticals, the size of the chamber can be modified so that about 25-150 μL of the solution can be delivered per actuation, which meets claim 19. See p. 1688, 6th par. – p. 1689, 1st par.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the anti-acne spray of the combined references by designing the size of the chamber as motivated by Sciarra because of the expectation of successfully adjust the delivered amount per actuation for a suitable dosage.

Response to Arguments/Declaration

Applicant's arguments with respect to claims 1, 2, 4, 5, 7-11, 13, and 15-22 have been considered but are moot in view of the new ground(s) of rejection.

Examiner fully considered the arguments and the declaration filed on November 4, 2003, but views that the arguments are unpersuasive to place the application in an allowable condition.

The fact that the composition itself is not known is not the legal standard to determine what would have been obvious to a skilled artisan in view of the collective teachings of available references at the time of the invention. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For example, it is well known in the art to treat acne in the body area other than face by spraying a solution containing a conventional anti-acne active. See Fitzjarrell and Kozak. Fitzjarrell is no longer used as the primary reference in view of a new reference, Kozak, which examiner believes shows stronger teaching. Formulating salicylic acid in a water/ethanol vehicle within the known pH range for treating acne is also well known. See Briggs.

While it is true that Briggs' "preferred" pH is lower than 5, examiner respectfully points out that it is well known in patent law that preferred embodiments do not constitutes a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi, 440 F.2d 442, 169 U.S.P.Q. 423 (C.C.P.A.). The court in In re Gurley also held, "a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See 27 F.3d 551, 554, 31 U.S.P.Q. 2d 1130, 1132 (Fed. Cir. 1994); See also MPEP § 2123. In this case, formulating salicylic acid with in the pH range of 1-7 for topical use is well known, thus the present rejection in view of Briggs is proper.

While applicants assert that it would have been nonobvious to increase pH of level of the salicylic acid solution to reduce nasal irritation and coughing, examiner views that the there is no unexpected or surprising results in this case. Increasing pH to reduce irritation caused by salicylic acid is well known in pharmaceutical art. See Boettcher et al. (US 4287190), col. 2, lines 42-49.

Conclusion

No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
December 12, 2003

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

12/15/03